The National Safety First Initiative

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Safety is a primary concern of consumers and scientists regarding the development and use of genetically engineered agricultural products. Debates are polarized and could well become more so over such questions as will genetically modified organisms (GMOs) irreparably harm genetic diversity in wild relatives and land races? Will they harm human health and ecosystems? At the same time, there is concern over whether another StarLink™-type case will hit and hurt not just one company but the entire industry by eroding public confidence. And the challenge of achieving broadly accepted environmental- and food-safety standards is that much greater for the next generation of biotech products, for example crops and even fish engineered to produce drugs and industrial compounds.

At the University of Minnesota's Institute for Social, Economic, and Ecological Sustainability (ISEES), our experience in other policy areas leads us to believe that it is possible to address biosafety issues and realize the promises of agricultural biotechnology. A coalition of diverse partners have come together in the National Safety First Initiative with the goal of developing and instituting industry-wide, publicly trusted, and scientifically reliable safety standards.

The Initiative

The Initiative employs a representational, deliberative, and transparent process grounded in science. There are four fundamental aspects.

- Quick fixes to current biotech debates are not possible. We are convinced that the first step must be to break from the binary yes-or-no choice on biotech and food. No easy consensus has eluded others that we can somehow snatch. There are real differences of perspective on biotech-safety issues in American society, including within the scientific and business communities. Our starting point is to acknowledge the existence of these differences.

- The Safety First Initiative involves a forum and a process for identifying differences and then negotiating through them honestly in a collective effort to develop cross-industry safety standards.
- The Safety First Initiative draws from the history of safety work in various American industries that involve complex engineering processes. At the workshop that launched public deliberation of our proposed safety-first approach, economic historians and safety engineers and analysts reviewed safety successes and pitfalls from a broad range of industries. We looked at the steel, lead, aircraft, food manufacturing and nuclear-power industries. These experts deliberated with biotech and bio-safety experts and concerned parties from industry, academia, and public-interest groups on panels and in a variety of break-out groups to make recommendations to guide proactive safety governance in the recently emerged and diverse biotechnology industry. We learned that attention to safety has historically come from strong external pressures from consumers, politicians and various organizations as well as from enlightened leadership within industry. Some companies in the United States stuck too long to a "safety-second" approach that resulted in financial losses, liability problems and erosion of consumer confidence. And we also learned that in some companies—either a maverick firm, for example US Steel in the early 1900s, or a coalition of firms and external stakeholders, for example aircraft manufacturers in the late 1900s—took the lead in placing safety first as a smart business stratagem that eventually transformed industry as a whole. Therefore, the Safety First Initiative builds on a time-tested American approach. It seeks to recreate the systems that are in place in other industries that developed safety standards with consumer and public consultation and thus achieved improved safety records and built public trust of their products.
- The Safety First Initiative is a public/private-sector partnership that is neither pro-regulatory nor deregulatory.

After remarkably positive feedback and interest expressed by the wide spectrum of participants in our 2001 workshop, a coalition emerged from business, the public-interest, community, and academe to plan and conduct an innovative process for negotiating industry-wide safety standards.

Objectives

The Safety First Initiative intends to draw up the nation's first cross-industry and publicly trusted standards for *designing, producing, and monitoring biotech products*, with safety a primary criterion throughout: from the early stages of designing a genetic construct at the lab bench through R&D and the elaborate processes involved in developing a stable GM variety or line through pre-market regulatory approval and post-market monitoring. Long-established principles of safety engineering offer a series of logical and well tested steps

for addressing contentious and complex issues involved in the manufacture of safe products.

The Safety First Initiative plans to organize cross-sectoral working groups that will negotiate similar elements of environmental and food-safety standards for GMOs in agriculture and aquaculture. These elements are as follows.

- Safety-criteria setting. These standards set the safety objectives from which follow the safety standards. It involves systemic risk analysis and planning to reduce risk, emphasizing what can be done to build safety from the outset to the design of genetic constructs and the choice of traits to modify.
- Verification standards. Prior to marketing, these standards address whether the product meets safety objectives to reasonable, measurable levels. Verification standards drive the design of scientific, reliable tests to fully challenge the product, drawing on the best available science from all relevant fields. Obviously, verification standards also must address questions about quality and type of data obtained from these verification tests.
- Follow-up standards. These address uncertainty, recognizing that even the best criteria and verification standards cannot anticipate all problems. Therefore scrupulous monitoring of a product in all its uses is needed, with the monitoring system designed to be practical and cost effective, targeting the most likely problematical areas. Such an approach fosters timely discovery of problems and early application of corrective measures.
- Safety leadership standards. These aim to ensure that the prior three types of standards are implemented consistently and properly. This involves, for example, establishment of rigorously trained and independently certified safety engineers who would be valued employees of companies as well as in government regulatory agencies. Such professionals—with independent certification—exist in other industries, for example in companies that manufacture and install complex aircraft components. And safety-conscious leadership at all management levels is an essential element.

Although pioneering firms have not received appropriate recognition for their efforts, we recognize that some agricultural biotech companies have already established one or more of these elements, providing the foundation for an industry-wide program of safety leadership.

Caveats

Two important caveats affect the negotiation of these standards. First is the issue of what is safe enough. One hundred percent safety can never be guaranteed. Defining what is safe enough will be a major objective of the representative deliberative process, involving negotiating an acceptable balance point between potential benefits—or, preferably, documented benefits—and the assurance level of safety for a given GM product. The second caveat

involves the distinction between non-living and living materials, because we are drawing on safety-engineering principles for manufactured non-living products. Qualitative differences exist between products derived from living organisms—such as foods derived from GMOs—and those from inanimate source materials. Our challenge is to draw on the history and rigorous methods of safety engineering of inanimate materials and apply lessons, where appropriate, to biological products.

How does this relate to HACCP[1]? There are several overlaps, and we plan to carefully study the HACCP process—which was designed to address safety issues in foods—focusing on food production from biological materials.

Inclusive Deliberations

The partners in our coalition recognize that achieving public trust in GM products that will be vetted through safety standards that will emerge from the initiative will entail important roles for the government and the public. For instance, government oversight should reinforce motivation for industry safety programs to be scientifically reliable, responsible, and responsive. Regarding public participation, the initiative involves transparent and inclusive deliberation, taking a cue from the airline industry where cross-sectoral working groups have been organized, including participants from business, consumer and public-interest groups and government agencies. Over a two-year period standards and procedures for industry-wide safety programs were negotiated, which, because there had been such an inclusive deliberative process, were endorsed by all parties. Companies adopted the standards and, in fact, went to their regulatory agency, the FAA, who rapidly incorporated them into the details of their regulations.

Similar inclusive deliberations have also been used for periodic review to update industry-wide standards in light of new information. Thus, the biotech industry can benefit from other engineering industries that have discovered that an open process grounded in science wins every time—in the long term reducing costs of product development and approval.

The Initiative's Executive Advisory Board is a partnership of prominent leaders of diverse private and public sectors. The co-chairs are Chuck Johnson, retired vice-president of DuPont, formerly with Pioneer HiBred, and Tim Penny, former US Congressman and presently director of the Humphrey Policy Center here at the University of Minnesota. Other members of the board are John Block, former US Secretary of Agriculture, Margaret Mellon, the program director of the food and environment program at the Union of Concerned Scientists, Vin Webber, former Congressman and co-director of Empower America, and John Woodhouse who recently retired as CEO of Sysco Corporation. The charge of the Executive Advisory Board is to provide

[1]Hazards Analysis and Critical Control Points.

advice on planning and oversight for the Steering Committee and the Initiative's outcomes. They are providing important advice on the substantive and procedural aspects of a plan for moving forward.

On the Steering Committee are leaders from large companies such as Syngenta and DuPont, from small new biotech companies including ProdiGene, and from the very small Cape AquaCulture Technologies. It is important that the standards that emerge from this initiative do not have an exclusionary effect on small biotech firms. When approached, the president of Cape AquaCulture Technologies, Bob Curtis, was immediately interested as it was an opportunity to get over a difficulty that his company was in. Because of recent media focus on consumer jitters over genetically engineered salmon that are expected to receive government approval, venture capitalists and other investors have been uncertain about investing in the biotechnology that he would like to apply in fish. He was looking for a way to show that his is a responsible company, and, by contributing to the development of standards that would be applied across industry, he would have a means of allaying fears. And, interestingly, some investors have quietly been checking in with us and asking to stay apprised, because they seek publicly vetted procedures for guiding their decisions.

The Steering Committee includes representatives from the world of commodity farming, from organic farming, consumer organizations, other NGOs, and academia. Jean Kinsey, director of the Food Retail Industry Center and professor of applied economics at the University of Minnesota—a speaker at this conference—is one of the members of the steering committee, as is John Howard—also a speaker—chief scientific officer at ProdiGene. The members of the Steering Committee are committed to furthering the Safety First Initiative and to maintaining communication links with the communities they represent. Each has important experience and perspectives that will shape and the Initiative's work and outputs. The committee is charged to provide oversight on the cross-representational working groups—including the negotiation process—and their outputs. The Steering Committee will carefully review the standards drawn up by the working groups, and problems will be returned to the working groups. Ultimately the Executive Advisory Board will review the standards before release.

Modus Operandi

The Executive Advisory Board and Steering Committee convened for the first time on April 22, 2002, to initiate a draft plan for developing industry-wide safety standards and discuss *modus operandi*.

The cross-sectoral working-group negotiations will focus on (i) the broadest general safety principles applicable to the range of GM products that the Initiative will address, and on (ii) product-specific standards that will be tailored to issues raised by particular GM products that the initiative will address.

Each company that adopts standards for these two levels will accordingly create their own standards for use at the company-project level. We will not be involved in how they decide to meet these standards.

The ISEES staff will provide the Safety First Initiative with administrative and managerial support and will provide professional facilitation at all meetings. Some staff members, including the author, have expertise in biosafety science and technical aspects, and we work closely with a leading system safety engineer from the aircraft industry. The ISEES staff will work with the Steering Committee to identify, invite and bring together working group members. We envision four working groups meeting in parallel, with communication between groups and with the Initiative leadership. The reason for four main working groups relates to the four central elements described above. Each working group will have sub-working groups on specific products.

The working groups will be cross-sectoral teams with various technical expertise but will also represent consumer interests. Furthermore, they will put themselves in the shoes of a company safety engineer: how should the product be designed to ensure maximum safety from the outset—what will be the R&D needs—what will be the government-approval needs—and what aspects will ensure broad public acceptance?

There were two major outcomes from the April 22, 2002, meeting. The Board and Steering Committee provided a frank critique of our draft plan, offering various personal perspectives. After working through some questions and mid-course corrections, they gave strong and clear endorsement of the Initiative's goals and substance, and the proposed approach: *substance* in terms of the goal of developing industry-wide safety standards, and *process* in terms of cross-sectoral transparent deliberation. The second major outcome was the consensus to focus the Initiative on two types of GM products:

- crops providing non-food products, from pharmaceuticals to industrial materials (with the possibility that this might include farm animals), and
- food products from genetically modified fish and shellfish.

Over the next 6 months the Initiative will concentrate on forming and convening the working groups and thus move into the functional phase of negotiating safety standards.